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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/024,070	12/18/2001	Joseph F. Petolino	50,518 DIV1	4280

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DOW AGROSCIENCES LLC
9330 ZIONSVILLE RD
INDIANAPOLIS, IN 46268

EXAMINER

MEHTA, ASHWIN D

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 01/29/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/024,070

Applicant(s)

PETOLINO ET AL.

Examiner

Ashwin Mehta

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 December 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Specification

1. The specification fails to comply with the sequence rules of 37 CFR 1.821-1.825.

Numerous nucleotide sequences appear, for example on pages 23, 25, 40, 42, 43, 46-50, 53, and 54, which must be referred to by sequence identifiers.

Claim Objections

2. Claim 11 is objected to because of the following informality: a recitation such as --set forth in -- appears to be missing after the word "sequence" in line 2. Appropriate correction is required.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

3. Claims 10 and 11 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1 and 2 of prior U.S. Patent No. 6,350,611 ('611). This is a double patenting rejection.

The instant claims are drawn towards a DNA construct functional in a plant cell comprising a transcriptional regulatory region comprising the DNA sequence of SEQ ID NO: 1,

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a gene of interest in sense or antisense orientation; and a transcriptional regulatory region comprising the DNA sequence of SEQ ID NO: 1. Patented claims 1 and 2 of '611 have the same scope. The nucleotide sequence set forth in SEQ ID NO: 1 of the instant application and the patent are identical.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 8 and 11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 8: the recitation "plant cell aggregate is initiated on solid medium" renders the claim indefinite. Claim 3 indicates that the aggregate is selected from a callus culture, and therefore is already formed.

In claim 11: the recitation "The transcriptional regulatory region according to claim 10" in lines 1-2 renders the claim indefinite. Claim 10 is directed towards a DNA construct, not a transcriptional regulatory region.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claim 9 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled

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in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claim is broadly drawn towards any fertile transgenic plant produced by the method of claim 3.

The specification describes a method for transforming Type I and II maize callus and Type I rice callus, and embryogenic callus from cotton, using silicon carbide whisker fibers. Transgenic plants were regenerated from the transformed maize and rice callus tissues (Examples 1-12).

However, the specification does not describe all fertile transgenic plants produced by the claimed method. The structures of all such transgenic plants, and their functions, are not described. While the specification describes a whisker-mediated method to transform callus tissue from maize, rice, and cotton, the structures and method itself is not a description of the transgenic plants that can be produced from the method. The transgenic plants encompassed by the claim may comprise any type of transgene, which can confer any type of property or change to the plant, all of which are not described. The structures and functions of all such plants are not described. Further, the plants encompassed by the claim include those that can be transformed with any transgene, including those that have yet to be discovered. Such transgenes are obviously not described. Given the breadth of the claims encompassing all fertile transgenic plants produced from the claimed method, and lack of guidance as discussed above, the specification fails to provide an adequate written description transgenic plants encompassed by the claim.

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6. Claims 1-3 and 6-9 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for transformation of cells from rice and maize Type I and Type II callus and embryogenic cotton callus, does not reasonably provide enablement for transformation of any other plant cell types, or for regeneration of all plant cell types. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The claims are broadly drawn towards the a method for transforming any plant cell selected from Type I, Type II, hypocotyl-derived or cotyledon-derived callus culture of any plant, or from a meristem, pollen, cotyledon, or germ cell tissue of any plant, and inserting DNA into said cell by whisker-mediated transformation; or wherein the transformed cell is further regenerated into a fertile transgenic plant.

The specification describes a method for transforming Type I and II maize callus, Type I rice callus, and embryogenic cotton callus, using silicon carbide whisker fibers. Transgenic plants were regenerated from the transformed maize and rice callus tissues (Examples 1-12).

However, the specification does not enable the transformation of other cell types. A number of variables, such as the concentration of whisker fiber suspension and vortex time and strength and preincubation in osmotic medium, need to be determined for successful transformation with this method. It is unpredictable whether the same conditions used for the transformation of the rice, maize and cotton calli can also be applied to all other cell types. It is also unpredictable whether all cell types can be transformed by the procedure. For example, Hess et al. (Plant Sci., 1990, Vol. 72, pages 233-244) teaches that because pollen contains high concentrations of DNases, transformation attempts using naked DNA have been unsuccessful

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(page 233). Further, Stewart (Stewart, Integrated Events In The Flower And Fruit, In Cotton Physiology, pages 261-300, J.R. Mauney and J. McD. Stewart, Eds., The Cotton Foundation, Pubs., Memphis, TN) teaches that pollen cells from dry stigma pollen plants, such as cotton, are extremely sensitive to moisture and rupture upon contact with water (page 270). Such pollen would be expected to rupture in the transformation conditions taught in the specification. The specification also teaches that non-embryogenic callus cannot be used to regenerate plants (page 12, lines 2-5). In the absence of further guidance, undue experimentation would be required to transform all cell types from any plant species using whisker fibers. Further, the specification does not enable the regeneration of all plant cell types. The lack of regenerative ability is a reason why plant transformation methods cannot be successfully used to produce transformed plants of all plant species. Potrykus (Annu. Rev. Plant Physiol. Plant Mol. Biol., 1991, Vol. 42, pages 205-225) discusses parameters the limit the ability of plant cells types to be transformed and regenerated (pages 206-209). The instant specification does not teach, for example, how one skilled in the art can regenerate any cell type from all plant species. See Genentech, Inc. V. Novo Nordisk, A/S, 42 USPQ2d 1001, 1005 (Fed. Cir. 1997), which teaches "the specification, not the knowledge of one skilled in the art" must supply the enabling aspects of the invention.

Additionally, claim 1 reads on the selection and transformation of a single cell ("at least one cell" in line 3), which suggests a 100% transformation efficiency. This level of efficiency is not reflected in the data shown in the Examples. Numerous cells will rupture during the vortexing step with the whisker fibers, and other steps. Examples of reproducible transformation procedures involving just a single cell are lacking in the prior art. It is suggested that the claim be amended to read on the use of more than one cell with the method. Given the breadth of the claims encompassing transformation of a cell derived from Type I and Type II callus cultures of

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any plant, any type of hypocotyls- or cotyledon-derived callus culture from any plant, any meristem, pollen, cotyledon, and germ-cell tissue from any plant, regeneration of all plant cell types, unpredictability of the art and lack of guidance of the specification, undue experimentation would be required by one skilled in the art to make and use the claimed invention.

Claim Rejections - 35 USC § 102 & 103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 1-3, 5, 8, and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Frame et al. (Plant J., 1994, Vol. 6, pages 941-948).

The claims are broadly drawn towards the the whisker-mediated transformation of a cell from Type I, Type II, hypocotyl-derived or cotyledon-derived callus culture of any plant, or from

a meristem, pollen, cotyledon, or germ cell tissue of any plant; or further wherein the callus is initiated on solid medium; and a fertile transgenic plant regenerated from the transformed cells.

Frame et al. teach fertile transgenic maize plants produced by whisker-mediated transformation of suspension cells derived from a maize Type II callus culture. The transgenic plants were regenerated from the transformed cells. The callus was initiated on a solid medium (pages 943-947).

8. Claim 9 is rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Kuehnle et al. (Plant Cell Rep., 1992, Vol. 11, pages 484-488).

The claim is broadly drawn towards any fertile transgenic plant produced by whisker-mediated transformation of a plant cell aggregate from a Type I, Type II, hypocotyl, or cotyledon callus culture.

Kuehnle et al. teach transgenic Dendrobium orchid plants, transformed via particle bombardment (pages 484-485). The plants taught by Kuehnle et al. differ from the claimed plants in their production from bombarded protocorms rather than whisker-mediated transformation. However, the process of making the claimed plants does not distinguish the plants themselves from those taught by the reference. The transgenic plant produced using the method of Kuehnle et al. is indistinguishable from the plant produced using the claimed method. See In re Thorpe, 227 USPQ 964,966 (Fed. Cir. 1985), which teaches that a product-by-process claim may be properly rejectable over prior art teaching the same product produced by a different process, if the process of making the product fails to distinguish the two products. Thus, the claimed invention was clearly prima facie obvious as a whole to one of ordinary skill in the art, if not anticipated by Kuehnle et al.

9. Claims 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Frame et al. in combination with Ishida et al. (Nature Biotech., 1996, Vol. 14, pages 745-750) and Firoozabady et al. (Plant Mol. Biol., 1987, Vol. 10, pages 105-116).

The claims are broadly drawn towards the whisker-mediated transformation of a cell from Type I, Type II, hypocotyl-derived or cotyledon-derived callus culture of any plant, or from a meristem, pollen, cotyledon, or germ cell tissue of any plant; or further wherein the callus is initiated on solid medium; and a fertile transgenic plant.

Frame et al. teach fertile transgenic maize plants produced by whisker-mediated transformation of suspension cells derived from a maize Type II callus culture. The callus was initiated on a solid medium. Frame et al. also suggest that the method may be used with any species with regenerable suspension cultures (pages 943-947).

Frame et al. does not teach Type I callus culture.

Ishida et al. teaches Type I callus culture of maize (page 745).

Firoozabady et al. teach *Gossypium hirsutum* cotyledon callus cultures (pages 107-108).


It would have been obvious and within the scope of one of ordinary skill in the art at the time the invention was made to use the whisker-mediated transformation method of Frame et al. to transform other cell types, including the Type I callus of Ishida et al. or the cotyledon-derived cotton callus of Firoozabady et al. and regenerated transgenic plants therefrom. One would have been motivated to use the method with other plants and cell types, including callus cultures from cotton hypocotyl tissue, given the suggestion of Frame et al. that it can be used with other species for which regenerable cultures exist.

10. Claims 1-11 are rejected.

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Contact Information

Any inquiry concerning this or earlier communications from the examiner should be directed to Ashwin Mehta, whose telephone number is 703-306-4540. The examiner can normally be reached on Mondays-Thursdays and alternate Fridays from 8:00 A.M to 5:30 P.M. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at 703-306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 and 703-872-9306 for regular communications and 703-872-9307 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.


ASHWIN D. MEHTA, PH.D
PATENT EXAMINER

January 25, 2003